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Michael E McClurken

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EXAMINER

MURO, SAMANTHA A

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

04/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,947	Applicant(s) MCCLURKEN ET AL.	
	Examiner SAMANTHA MURO	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/20/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/20/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 68-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,953,461. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent 6,953,461 and the instant application all recite the same basic structure of first and second movable jaws with tissue grasping surfaces and fluid passages along with a permutation of similar elements throughout. The various combinations are all deemed to be obvious variants as no criticality is afforded to any particular combination of elements in any particular patent.

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Claims 68-87 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/532,704; 10/914,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because these applications and the instant application all recite the same basic structure of first and second movable jaws with tissue grasping surfaces and fluid passages with a permutation of similar elements throughout. The various combinations are all deemed to be obvious variants as no criticality is afforded to any particular combination of elements in any particular patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 68-80, 82-83, and 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al (5,810,811) in view Mulier et al (6,096,037).

Referring to claim 68, Yates et al teaches a tissue grasping device (Figure 1) comprising: a first jaw (32) and a second jaw (34), at least one of the jaws (32) being movable toward the other jaw (34); the first jaw (32) having a first jaw tissue grasping surface (33/37/56) and the second jaw (34) having a second jaw tissue grasping surface (35) (Col. 6, lines 40-58), the tissue grasping surface of each jaw comprising an electrically insulative surface (Col. 7, lines 40-45 and Col. 8, lines 13-29; Figure 1); a first electrode (52) and a second electrode (18/18a), the first (52) and second electrodes (18/18a) configured to have opposite polarity when electrically coupled to a radio frequency power source (60 – shown in Figure 2) and positioned for an electrical current from the first and second electrodes to flow in tissue grasped between the tissue grasping surfaces substantially parallel to the tissue grasping surfaces and across a width of the tissue grasping surfaces (Col. 6, lines 36-61 and Col. 8, lines 13-29; Figures 2 and 6); the first jaw tissue grasping surface (33/37/56) and the second jaw tissue grasping surface (35) medial to the first electrode (52) and the second electrode (18/18a) (Figure 6). Additionally, Yates et al discloses various arrangements of electrodes which may be provided on the jaw surfaces (see Figures 6, 11-14, and 17-19). Yates et al fails to expressly state having at least one fluid passage.

Mulier et al teaches an analogous tissue grasping device (Figure 2) that is fluid-assisted. Mulier et al teaches a fluid-assisted tissue grasping device that comprises a

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first jaw (44/48) and a second jaw (46/50) and a first electrode (47) and second electrode (49) (Col. 4, lines 34-47 and lines 55-64). Mulier et al teaches at least one fluid delivery passage (52 and 54) and at least one fluid outlet (166) (Col. 4, line 55 through Col. 5, line 12; Col. 5, lines 25-35; Figures 3-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates et al, to be fluid-assisted having a fluid delivery passage and fluid outlet, as taught by Mulier et al, in order to maintain relatively consistent maximal electrical contact areas, substantially prevent hot spots and allow higher power than soft coagulation, and further allows for little to no arcing, cutting smoke or char (Col. 5, lines 53-56).

Referring to claim 69, the modified Yates reference teaches wherein the at least one fluid outlet (166) further comprises a first fluid outlet and a second fluid outlet (Figures 4-5 of Mulier et al).

Referring to claim 70, the modified Yates reference teaches at least one of the first fluid outlet and the second fluid outlet is used to provide a fluid onto the first electrode or the second electrode, respectively (Col. 4, lines 55 through Col. 5, line 7; Figures 3-5 – Mulier et al).

Referring to claim 71, Yates fails to teach a fluid outlet partially defined by an electrode. However, Mulier et al teaches wherein at least one of the first fluid outlet and

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second fluid outlet (166) is defined by the first or second electrode (Col. 4, line 65 through Col. 5, line 10; Figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates et al, to have a first or second fluid outlet defined by the first or second electrode, as taught by Mulier et al, in order to maintain relatively consistent maximal electrical contact areas, substantially prevent hot spots and allow higher power than soft coagulation, and further allows for little to no arcing, cutting smoke or char (Col. 5, lines 53-56).

Referring to claim 72, Yates teaches wherein the first jaw tissue grasping surface (33/37/56) has a first edge opposite a second edge (shown best in Figure 6). Mulier et al teaches wherein at least one of the first fluid outlet and the second fluid outlet is used to provide a fluid between the first electrode and the first edge of the first jaw tissue grasping surface or between the second electrode and the second edge of the first jaw tissue grasping surface, respectively (Col. 4, lines 55 through Col. 5, line 10; Figures 3-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates et al, have the fluid outlet provide fluid between the electrode and edge of the grasping surface, as taught by Mulier et al, in order to maintain relatively consistent maximal electrical contact areas, substantially prevent hot spots and allow higher power than soft coagulation, and further allows for little to no arcing, cutting smoke or char (Col. 5, lines 53-56).

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Referring to claim 73, Yates fails to teach a fluid outlet. Mulier et al teaches wherein the first fluid outlet and the second fluid outlet (166) is used to provide a fluid into a first reservoir or a second reservoir, respectively (tube shown in Figure 4 that fluid passage 54 feeds into). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates et al, to include fluid outlets that are used to provide a fluid into a reservoir, as taught by Mulier et al, in order to maintain relatively consistent maximal electrical contact areas, substantially prevent hot spots and allow higher power than soft coagulation, and further allows for little to no arcing, cutting smoke or char (Col. 5, lines 53-56).

Referring to claim 74, Yates fails to teach a fluid outlet. Mulier et al teaches wherein: at least one of the first reservoir and the second reservoir is adjacent the first electrode or the second electrode, respectively (Col. 4, line 65 through Col. 5, line 8; Figure 4). By modifying the Yates reference to include a reservoir (tube shown in Figure 4 that fluid passage 54 feeds into), it would be adjacent the first or second electrode.

Referring to claim 75, Yates teaches wherein the first jaw tissue grasping surface (33/37/56) has a first edge opposite a second edge (shown best in Figure 6). Mulier et al teaches wherein a portion of one of the reservoir (tube shown in Figure 4 that fluid passage 54 feeds into) is between the electrode and the edge of the jaw tissue grasping surface (Col. 4, line 65 through Col. 5, line 8; Figure 4). It would have been obvious to

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one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates et al, to have a portion of the reservoir between the electrode and the edge of the jaw tissue grasping surface, as taught by Mulier et al, in order to ensure that the fluid is position correctly in order to maintain relatively consistent maximal electrical contact areas, substantially prevent hot spots and allow higher power than soft coagulation, and further allows for little to no arcing, cutting smoke or char (Col. 5, lines 53-56).

Referring to claim 76, Yates teaches wherein the first jaw tissue grasping surface (33/37/56) has a first edge opposite a second edge (shown best in Figure 6). The modified Yates reference teaches wherein the first electrode is spaced along the first edge of the first jaw tissue grasping surface by a first reservoir. Mulier et al teaches placing the fluid reservoir (tube shown in Figure 4 that fluid passage 54 feeds into) in the center of the jaw tissue grasping surface. As such, when modifying the tissue grasping surface, as taught by Yates, the reservoir, as taught by Mulier, would be located in the approximate center of the tissue grasping surface which would therefore have the first electrode (18) be spaced along the first edge of the first jaw tissue grasping surface (33/37/56) by the reservoir.

Referring to claim 77, Yates teaches wherein the first jaw (32) has a first side portion (middle portion of Figure 6, side where element 56 is located) opposite a second side portion (left side of Figure 6, side where element 37 is located); the first electrode

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(52) being on the first side portion (left side of Figure 6, side where element 37 is located) of the first jaw (32); the second electrode (18/18a) being on the second side portion (left side of Figure 6, side where element 37 is located) of the first jaw (32) (Figure 6). Mulier et al teaches having a first and second fluid outlet, which teaches having the plurality of outlets (166) in approximately the center of the jaw to provide fluid on the entire jaw surface (Col. 5, lines 1-49; Figures 3-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the first jaw having a first and second electrode, as taught by Yates, to have a first and second fluid outlets on either side of the first jaw to provide fluid, as taught by Mulier et al, in order to allow the conductive solution to be infused onto and into the tissue (Col. 5, lines 53-56).

Referring to claim 78, Yates fails to teach a fluid delivery passage. Mulier et al teaches wherein the at least one fluid delivery passage comprises a first fluid delivery passage (52) and a second fluid delivery passage (54); the first fluid outlet (166) in fluid communication with the first fluid delivery passage (52); and the second fluid outlet (166) in fluid communication with the second fluid delivery passage (54) (Col. 4, line 55 through Col. 5, lines 37). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates, to have two separate fluid delivery passages with their own respective fluid outlets, as taught by Mulier et al, in order to provide enough conductive solution to both jaws (Col. 5, lines 38-60).

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Referring to claim 79, Yates fails to teach a fluid delivery passage. Mulier et al teaches wherein the first fluid delivery passage (52) and the second fluid delivery passage (54) is defined by an electrode (Col. 4, lines 55-64; Figures 3-4). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the electrodes, as taught by Yates, to include fluid delivery passages, as taught by Mulier et al, in order to provide the advantages of using a conductive solution (Col. 5, lines 38-60).

Referring to claim 80, Yates teaches device of claim 68 wherein the second electrode (18/18a) comprises a hollow structure (Figure 6).

Referring to claim 82, Yates teaches device of device of claim 68 wherein: the tissue grasping surface (33/37/56) of at least one jaw (32) has one or more serrations (Figure 6).

Referring to claim 83, Yates teaches the device of claim 68 wherein: the first jaw (32) comprises a first jaw support structure (55) beneath the first jaw tissue grasping surface (33/37/56), the first jaw support structure (55) having a first side portion opposite a second side portion; the first electrode (52) being along the first side portion of the first jaw support structure; and the second electrode (18/18a) being along the second side portion of the first jaw support structure (Col. 7, lines 8-20; Figure 6).

Referring to claim 86, Yates teaches a device of claim 68 further comprising: a tissue treatment indicator which provides an output related to the level of treatment of tissue (Col. 9, lines 6-51; Figure 10).

Referring to claim 87, Yates teaches a device of claim 68 further comprising: a cutting mechanism (11) (Col. 6, line 19 and Col. 6, line 62 through Col. 7, line 7; best seen in Figure 2).

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al (5,810,811) in view Mulier et al (6,096,037) as applied to claim 68 above, and further in view of Eggers et al (5,484,436).

Referring to claim 81, Yates and Mulier fail to expressly teach that the tissue grasping surface includes a hydrophobic surface. However, Eggers et al teaches an analogous tissue grasping device wherein a hydrophobic surface is used, such as Teflon (Col. 6, lines 64-67). Yates specifically teaches using Teflon on the tissue grasping surfaces (Col. 7, lines 34-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping surface, as taught by Yates, to be hydrophobic, as taught by Eggers, in order to prevent the ingress of biological fluid or saline solution in the instrument (Col. 6, lines 64-67).

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Claims 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al (5,810,811) in view Mulier et al (6,096,037) as applied to claim 68 above, and further in view of Weaver (5,693,052).

Referring to claim 84, Yates teaches wherein at least one jaw (32) comprises a first jaw support structure (55) beneath the first jaw tissue grasping surface (33/37/56) however fails to expressly teach a heat sink. Weaver teaches an analogous tissue grasper instrument which uses a nickel-free high chromium coating as a heat sink (Col. 3, lines 1-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the support structure, as taught by Yates, to have a heat sink coating, as taught by Weaver, in order to minimize heat buildup at the treatment site (Col. 3, lines 18-23).

Referring to claim 85, Yates and Mulier fails to expressly teach a standoff. . Weaver teaches an analogous tissue grasper instrument which uses a nickel-free high chromium coating, which inhibits tissue from physically contacting the electrode. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the electrodes, as taught by Yates et al, to have a stand-off coating, as taught by Weaver, in order to minimize heat building up and minimize sticking of debris to the electrodes (Col. 3, lines 18-23).

Response to Arguments

Applicant's arguments filed November 18, 2009 have been fully considered but they are not persuasive. Medial is defined as "pertaining to the middle; in or towards the middle." As such, since the tissue grasping surfaces are in the middle of the electrodes since they are located directly beneath of them, as shown best in Figure 6, they are medial to the electrodes. The examiner points to Figure 6, which includes the element numbers in the rejection, and only points to Figures 11-14 and 19 as examples of other configurations. Furthermore, Yates specifically teaches that the first electrode (52) acts as the first pole and is located longitudinally with respect to the jaw member (32). Jaw member (32) also comprises the second electrode (18) which acts as the second pole. Since these electrodes are located longitudinally down the jaw member the electrical current will flow in tissue grasped between the tissue grasping surfaces parallel to the tissue grasping surfaces and across a width of the tissue grasping surface (Col. 6, lines 35-62; Figure 6).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMANTHA MURO whose telephone number is (571)270-7480. The examiner can normally be reached on Monday - Friday 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/S. M./
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739